IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number: 7,766,012

Issued: August 3, 2010

Name of Patentee: Gerhard Scheuch et al.

Title of Invention: DEVICE FOR THE CONTROLLED INHALATION OF THERAPEUTIC AEROSOLS

Mail Stop Petition
Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandra VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR APPLICANTS MISTAKE (37 CFR 1.323)

1. It is noted that an error appears in the patent of a typographical nature or character as more fully described below and occurred in good faith and correction thereof does not involve such changes in the patent that would constitute new matter or would require re-examination, and a certificate of correction is requested.

2. Attached are copies of the following:

   - Copy of the relevant claims for issued patent 7,766,012 (Columns 3-4).
   - Copy of office action response dated June 19, 2009

3. Attached in duplicate is Form PTO-1050 with at least one copy being suitable for printing.

4. The exact page and line numbers where errors occur in the application file are:

   Claim 1 (Column 4, line 32): "maneuvers" should read "maneuver"

5. Regarding the typographical error in issued claim 1, the correct wording was submitted for claim 25 in the attached office action response dated June 19, 2009.

6. Please send the Certificate to:

Meghan Van Leeuwen
Brown & Michaels PC
400 M&T Bank Bldg., 118 N. Tioga Street
Ithaca, New York 14850

7. Included is the fee of $100.00 as required by 35 CFR 1.20(a).

By: /mav #45612/
Meghan Van Leeuwen, Reg. No. 45,612
Attorney of Record
Date: August 10, 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: 7,766,012

DATED: August 3, 2010

INVENTOR(S): Gerhard Scheuch et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4, line 32: replace "maneuvers" with "maneuver"

MAILING ADDRESS OF SENDER: **PATENT NO. 7,766,012**

Brown & Michaels, PC
400 M&T Bank Building
118 North Tioga Street
Ithaca, New York 14850-4343

(PTO FORM 1050)

UNITED STATES PATENT AND TRADEMARK OFFICE

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It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

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(PTO FORM 1050)

In a further preferred embodiment, the memory medium **10** is reprogrammable in order to provide adapted parameters for the correct breathing maneuver if the pulmonary function of the patient **20** changes.

Preferably, the inhalation device **12** according to the present invention prevents an overdose, for example by presetting an action period or an action blockage, e.g. on the memory medium **10**. This prevents the activation of the inhalation device **12** by the patient **20** as long as the necessary period of time between two successive inhalations has not lapsed. Preferably, the memory medium **10** also serves for recording errors. It records for example whether the atomizer pressure deviates too much from a desired range or whether the required atomizer pressure could not be built up at all. Moreover, the memory medium **10** preferably records a possible safety cutoff when the pressure at the mouthpiece **18** (positive pressure respiration) gets too high. In a further preferred embodiment, a too high deviation of the flow (either the atomizer flow of the aerosol or the auxiliary flow of the additional air supplied to the aerosol air or the sum of both flows) is recorded or an error message if one of the aforementioned flows for the inhalation could not be built up. Preferably, a termination of the inhalation is also recorded by the patient **20**.

Preferably, the designation of the drug to be inhaled is also stored on the memory medium **10**.

Moreover, according to a preferred embodiment, an access control for servicing is provided. Servicing software in the inhalation device **12** for is activated by means of a specific code in the memory medium **10**.

The inhalation device according to the invention offers the following advantages:

1. For each patient **20**, an individually agreeable and optimal inhalation manoeuvre is adjusted or pre-set;
2. By pre-setting individual parameters, different substances may be applied to different desired areas of the lung;
3. The release of the active ingredient is made more reproducible;
4. The optimal dose of the active ingredient is applied to the desired section of the patient's lung.
5. By programming different breathing maneuvers, different drugs may be inhaled with one device optimally and individually adapted for each patient **20**;
6. The inhalation device according to the invention may immediately be updated to new substances, new breathing maneuvers and changed respiratory flows;
7. In a memory medium **10**, such as a SmartCard, breathing maneuvers in the course of a therapy may be recorded and subsequently evaluated;
8. If the patient's pulmonary function changes, the inhalation device may easily be re-set to the changed basic condition;
9. The use of a propellant is not absolutely necessary.

An exemplary inhalation device that can be adapted for purposes of the present invention is disclosed in U.S. Pat. No. 5,161,524 to Evans, the disclosure of which is hereby incorporated by reference. Evans discloses a breath-actuated inhalator having a primary and a secondary air flow conduit. The portable dosage inhalator dispenses to a patient a predetermined amount of a pharmacologically active dry powder compound. The inhalator includes a housing defining an air exit end for insertion into the mouth of a patient. The inhalator also includes a primary air conduit within the housing and defining a venturi within the primary air conduit. The inhalator further includes a secondary air conduit within the housing adjacent the primary air conduit. The inhalator controls air flow velocity therethrough during inhalation by the patient. A regulator normally closes the secondary air conduit to air flow and is adapted to move between a first position where the secondary air conduit is substantially closed and a second position where the secondary air conduit is substantially open in response to air pressure differentials created in the venturi of the primary air conduit as a patient inhales through the air exit end of the housing.

According to the invention, all medicinal agents may be used which become effective either topically in the respiratory system or systemically. Suitable medicinal agents are analgesics, anti-angina agents, anti-allergic agents, antihistamines and anti-inflammatory agents, expectorants, antitussives, bronchodilators, diuretics, anticholinergics, corticoids, xanthines, oncotherapeutical agents as well as therapeutically active proteins or peptides, such as insulin and interferon.

The administration of medicinal agents for treating respiratory diseases, such as asthma, as well as prophylactics and agents for treating the mucosae of the tracheobronchial system is preferred. The administration of esters of retinol and vitamin A as described in EP-A- 0 352 412 is particularly preferred. The medicinal agents may be in their free form or in form of a pharmaceutically acceptable salt or ester. A further possibility consists in embedding the medicinal agent in liposomes.

The medicinal agents may be packaged with conventional, pharmaceutically acceptable excipients.

What is claimed is:

1. A method for administering a controlled inhalation of therapeutic aerosols for a patient during an adjusted breathing maneuvers comprising the steps of:

inputting into an inhalation device a plurality of inhalation parameters for the inhalation;

wherein the inhalation parameters are selected from the group consisting of:

a) a plurality of individual patient parameters for the patient;

b) a plurality of aerosol parameters; and

c) a combination of a) and b);

individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined amount of aerosol deposition in a lung of the patient, comprising the substeps of:

evaluating the inhalation parameters for the inhalation; and

adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of the lung of the patient during the controlled inhalation.

2. The method of claim **1**, wherein the step of adjusting is accomplished using at least one valve.

3. The method of claim **1**, wherein an air flow through the inhalation device is controlled based on the inhalation parameters.

4. The method of claim **1** further comprising the step of inhaling through the inhalation device by the patient.

5. The method of claim **1**, wherein the step of inputting comprises the substep of receiving the inhalation parameters through a modem.

6. The method of claim **1**, wherein the step of inputting comprises the substep of manually inputting the inhalation parameters.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

June 19, 2009

Serial No.	09/810,988
Applicant:	Gerhard Scheuch *et al.*
Filed:	March 16, 2001
Title:	DEVICE FOR THE CONTROLLED INHALATION OF THERAPEUTIC AEROSOLS
Art Unit:	3731
Examiner:	Clinton T. Ostrup
Confirmation Number:	7304
Attorney Docket No.:	RVOS-E1341US

HONORABLE COMMISSIONER OF PATENTS
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

In response to the Office Action dated March 20, 2009, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments of the Claims:

A detailed listing of all claims in the application is presented below. This listing of claims will replace all prior versions, and listings, of claims in the application. All claims being currently amended are submitted with markings to indicate the changes that have been made relative to immediate prior version of the claims. The changes in any amended claim are being shown by strikethrough (for deleted matter) or underlined (for added matter).

1-24. (Cancelled)

25. (Currently Amended) A method for administering a controlled inhalation of therapeutic aerosols for a patient during an adjusted breathing maneuvers ~~s~~ comprising the steps of:

inputting into an inhalation device a plurality of inhalation parameters for the inhalation;

wherein the inhalation parameters are selected from the group consisting of:

a) a plurality of individual patient parameters for the patient;

b) a plurality of aerosol parameters; and

c) a combination of a) and b);

individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined aerosol deposition in a lung of the patient, comprising the substeps of:

evaluating the inhalation parameters for the inhalation; and

adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation ~~aerosol~~ parameters such that an optimal dose of at least one active ingredient of at least one

aerosol is applied to a desired section of the ~~a~~ lung of the patient during the controlled inhalation~~; and~~

~~controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation~~.

26-27. (Cancelled)

28. (Previously Presented) The method of claim 25, wherein the step of adjusting is accomplished using at least one valve.

29-37. (Cancelled)

38. (Currently Amended) The method of claim 25, wherein an ~~the~~ air flow through the inhalation device is controlled based on the inhalation parameters.

39-41. (Cancelled)

42. (Previously Presented) The method of claim 25 further comprising the step of inhaling through the inhalation device by the patient.

43. (Currently Amended) A method for administering a controlled inhalation of therapeutic aerosols for a patient during breathing maneuvers comprising the steps of:

inputting into an inhalation device a plurality of individual patient parameters for the patient for the inhalation;

individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters to obtain a predetermined aerosol deposition in a lung of the patient, comprising the substeps of:

evaluating the individual patient parameters for the inhalation; and

adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the

inhalation device based on the individual patient parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of the ~~a~~ lung of the patient during the controlled inhalation~~; and~~

~~controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation~~.

44. (Currently Amended) A method for administering a controlled inhalation of therapeutic aerosols for a patient during breathing maneuvers comprising the steps of:

inputting into an inhalation device a plurality of aerosol parameters for the inhalation;

individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters to obtain a predetermined aerosol deposition in a lung of the patient, comprising the substeps of:

evaluating the aerosol parameters for the inhalation; and

adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the aerosol parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of the ~~a~~ lung of the patient during the controlled inhalation~~; and~~

~~controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation.~~

45. (Previously Presented) The method of claim 25, wherein the inputting step comprises the substeps of:

inserting a memory medium into the inhalation device; and

storing the inhalation parameters on the memory medium before the inhalation.

46. (Previously Presented) The method of claim 43, wherein the inputting step comprises the substeps of:

inserting a memory medium into the inhalation device; and

storing the individual patient parameters on the memory medium before the inhalation.

47. (Previously Presented) The method of claim 44, wherein the inputting step comprises the substeps of:

inserting a memory medium into the inhalation device; and

storing the aerosol parameters on the memory medium before the inhalation.

48. (New) The method of claim 25, wherein the step of inputting comprises the substep of receiving the inhalation parameters through a modem.

49. (New) The method of claim 25, wherein the step of inputting comprises the substep of manually inputting the inhalation parameters.

50. (New) The method of claim 45, wherein the memory medium also stores data from breathing maneuvers carried out.

51. (New) The method of claim 45, wherein the memory medium is selected from the group consisting of:

a) a SmartCard;

b) a FlashCard; and

c) a SmartLabel.

52. (New) The method of claim 45, wherein the memory medium is reprogrammable such that the individual patient parameters stored on the memory medium are adapted if a pulmonary function of the patient changes.

53. (New) The method of claim 45, wherein the memory medium also stores an action blockage pre-setting such that a period of time lapses between successive inhalations to prevent an overdose.

54. (New) The method of claim 45, wherein the substep of storing the inhalation parameters on the memory medium occurs prior to the substep of inserting the memory medium into the inhalation device.

55. (New) The method of claim 25, further comprising the step of controlling an air flow through the inhalation device during inhalation by the patient.

REMARKS

The office action of March 20, 2009 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 25, 28, 37-38, and 42-55 remain in this case, claims 25, 38, 43, and 44 being amended, claims 22-24, 29-30 and 35-37 being cancelled and claims 48-55 being added by this response. No new matter has been added. More specifically, claims 48-49 are the same as cancelled claims 23-24, claim 50 is the same as cancelled claim 22, claims 51-52 are the same as cancelled claims 29-30 and claims 53-54 are the same as cancelled claims 35-36. These claims have merely been renumbered so that they depend upon a preceding claim. New claim 55 is fully supported by the material previously incorporated by reference (from US Patent 5161524), and added to the specification in the office action response dated May 2, 2007. The amendments to claims 25, 43, and 44 are fully supported, for example by paragraph [0016] of the publication (2001/0037806) of the present application, as filed. The amendment to claim 38 was made to provide antecedent basis.

Claim Objections

2. The claims were objected to as being incorrectly numbered. Although Applicant disagrees that renumbering is necessary, claims 22-24, 29-30 and 35-36 have been cancelled, and replaced by new claims 48-54, which are identical to the cancelled claims. Reconsideration and withdrawal of the objection are respectfully requested.

Rejections under 35 U.S.C. §112

4. Claims 22-25, 28-30, 35-38 and 42-47 were rejected under 35 U.S.C. 112, first paragraph, as filing to comply with the written description requirement. Although the Applicant respectfully disagrees with this rejection (as explained in Applicant's response dated August 14, 2008), claims 25, 43 and 44 have been amended and claim 37 has been cancelled to overcome this rejection.

Reconsideration and withdrawal of the rejection of claims 22-25, 28-30, 35-38 and 42-47 are respectfully requested.

Rejection under 35 U.S.C. §102

6. Claims 24, 25, 28, 38 and 42-44 were rejected under 35 U.S.C. 102(e) as being anticipated by Brooker (6,269,810). Applicant respectfully disagrees with the rejection.

As amended, independent claim 25 claims, in part, "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined aerosol deposition in a lung of the patient, comprising the substeps of: evaluating the inhalation parameters for the inhalation and adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of the lung of the patient during the controlled inhalation" (emphasis added). Amended claims 43 and 44 similarly claim "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters to obtain a predetermined aerosol deposition in a lung of the patient, comprising the substeps of: evaluating the individual patient parameters for the inhalation; and adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of the lung of the patient during the controlled inhalation" and "individually adjusting the inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the aerosol parameters to obtain a predetermined aerosol deposition in a lung of the patient, comprising the substeps of: evaluating the aerosol parameters for the inhalation; and adjusting a breathing maneuver of the patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the aerosol parameters such that an optimal dose of at least one active ingredient of at least one aerosol is applied to a desired section of the lung of the patient during the controlled inhalation", respectively (emphasis added).

Brooker does not disclose individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined aerosol deposition in the lung of a patient.

In claims 25, 43, and 44, the breathing maneuver of the patient is adjusted, i.e. the inhalation device urges the patient to breath following the breathing maneuver as adjusted and given by the device. This is in clear contrast to Brooker. In the passages cited by the Examiner, Brooker clearly describes that the patient breathes as he/she likes: "with cooperation of the patient (in drawing a deep breath)…" (col. 6, lines 17, 18); "followed by a volume of air which makes up the latter part of each breath" (col. 6, lines 22, 23, irrespective of the size/volume of this latter part); and "The software will also cause the beeper or alarm to sound if sensor 29 does not detect any breaths for 10 seconds. This will assure that the patient is breathing properly…" (col. 14, lines 2 to 5). Thus, the patient is absolutely free to breath as he/she likes, and the breathing is just monitored to indicate if it is abnormal.

Even though Brooker conducts tests on the patient prior to administering the drug by inhalation (see col. 7, lines 33 to 35), the actual inhalation is not controlled by adjusting the breathing pattern. Based on the test results, the aerosol volume or the air to drug aerosol volume ratio is set (see col. 6, lines 30 to 40); however, the whole inhalation or aerosol deposition, respectively, fails if, after the tests, at actual inhalation, the patient breathes differently than before.

Furthermore, in amended claims 25, 43, and 44, a predetermined aerosol deposition in the lung is obtained. Brooker does not obtaining a predetermined aerosol deposition in the lungs of the patient. Brooker mentions in col. 6, lines 12, 13 "that the drug aerosol reaches the deep lung". While it may appear at first glance that this is a kind of predetermined aerosol deposition, there is actually no predetermined aerosol deposition disclosed in Brooker. Since the inhalation in Brooker depends on the patient's breathing, there is no way to assure in Brooker that any of the drug, let alone a predetermined amount, actually reaches the deep lung. The amount of aerosol deposition depends on how much of the air volume following the drug volume is inhaled by the patient. If the patient does not inhale a sufficient amount of air to "push" the preceding drug

volume into the lung, the drug volume simply does not reach the deep lung. Therefore, there is no predetermined aerosol deposition in Brooker.

Brooker does discuss tidal volume. "It has been found that it is especially useful for some therapies that the drug aerosol reaches the deep lung. The entire volume of each breath is called the 'inspired volume'. This inspired volume can be a normal breath, referred to as 'tidal volume', or could be a deep breath of much greater volume, referred to as a 'vital capacity' breath. With cooperation from the patient (in drawing a deep breath), the device enables this deep penetration by providing that the metered volume of drug aerosol from the plenum forms the first part of each inhaled breath (approximately equal to the tidal volume) and is followed by a volume of air which makes up the latter part of each inhaled breath (the remainder of the vital capacity). It has been determined that this air portion in the latter part of each breath tends to help push the initial drug portion down into the deep lung. If the drug made up most of the entire breath, then the latter part of each breath would not be delivered to the deep lung and may not be available for maximum benefit." (col. 6, lines 12-29). Part of Brooker's method calculates "the number of breaths required from the patient" (col. 7, line 28). Clearly, the patient's breathing accounts for the tidal volume and respiratory flow. The device is not able to adjust these parameters based on an individual patent. The device in Brooker only controls aerosol pulses, pulse lengths and the number of breaths. In addition, a major objective in Brooker is the safe inhalation of neoplastic drugs by capturing the exhaled aerosol. The inhalation device in Brooker is not intended for a routine inhalation at home.

In response to the arguments made in the last response, as well as Mr. Muellinger's declaration, the Examiner states "[s]ince the adjusted pulse would make up a portion of the respiratory flow or the tidal volume, and given that tidal volume is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied, the adjustment of the pulse would adjust the respiratory flow or tidal volume (at least to some extent)" (present office action dated March 20, 2009, page 11, lines 12-16, see also page 8, lines 7-12). Applicant agrees that the adjusted pulse would make up a portion of the tidal volume as it is the first part that is inhaled, as mentioned in col. 6, lines 17 to 24 of Brooker. Even accepting that the adjusted pulse would make up a portion of the tidal volume, however, it cannot be concluded that adjustment of the pulse would adjust the tidal volume to any extent. In

Brooker, the adjusted pulse (volume) cannot adjust the tidal volume as the tidal volume in Brooker is determined by the way the patient breathes. If the patient does not breathe regularly but has an irregular breathing pattern, the tidal volume for each breath is different despite having an adjusted pulse volume. In addition, the adjusted pulse would not make up a portion of the respiratory flow as it is just a volume aerosol and not a "flow". Thus, the Applicant respectfully submits that the Examiner's statement above is incorrect.

Brooker does not disclose adjusting flow rate or tidal volume using individual patient parameters or aerosol parameters. Brooker states that "[i]t will be remembered that the pulmonary dosing system of the present invention does not include a respirator or the like, and is intended for use with patients who can breathe normally." (col. 4, lines 31-35). The breathing pattern in Brooker is not adjustable in the device. The breathing pattern in Brooker is not controlled, since deposition is preferably measured during the inhalation treatment by using the radioactive tracer Tc99m. Once the data using the tracer has been collected, a physician is required to train and guide the patient. The device is not capable of being individually adjusted by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters.

By adjusting the respiratory flow or tidal volume of the inhalation device, the method of the present invention is able to optimize the dose of the active ingredient of an aerosol that is applied to a desired section of a lung of a patient, as claimed in claims 25, 43 and 44. Brooker does not disclose an optimal dose of at least one active ingredient of at least one aerosol being applied to a desired section of a lung of the patient during a controlled inhalation. As discussed in the Brand paper filed as part of an IDS dated July 11, 2006 and in the office action response dated August 14, 2008, it is very difficult to optimize dosage of an active ingredient for an aerosol from patient to patient without controlling the breathing pattern of the patient. "The study has shown that within the study population the inhaled air volume and flow rate were quite different. Consequently, **total particle deposition varied between 20 and 95%, depending on breathing patterns**." (Brand, 1999, Abstract, page 724). "The dose depends on many factors that are difficult to control; particle deposition in the lungs strongly depends on particle size, lung structure and breathing pattern, with the result that particle deposition and thus the deposited dose varies considerably among patients." (Brand, 1999, p. 724, second column, first

paragraph). "Although all patients were carefully trained at the beginning of their inhalation therapy to perform inhalations deeply and slowly, the breathing pattern was quite different among patients (Fig. 2)." (Brand, 1999, p. 726, second column, last paragraph). As discussed above, Brooker does not control or adjust tidal volume or respiratory flow. Therefore, Brooker does not disclose providing an optimal dose of at least one active ingredient of an aerosol to a desired section of a lung of a patient.

Brooker does not disclose each and every element of Applicant's claims 25, 43, and 44. Therefore, it is respectfully suggested that the rejection of independent claims 25, 43 and 44 as being anticipated by Brooker is overcome. Claims 28, 38, 42, and 49, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection of claims 24, 25, 28, 38 and 42-44 are respectfully requested.

Rejections under 35 U.S.C. §103

8. Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker in view of Servidio (5,598,838). Applicant respectfully disagrees, and believe the claims, as amended, are patentable over Brooker for the reasons given above in respect to the section 102 rejection of claim 25, from which claim 48 (previously claim 23) depends. The arguments above as to the novelty of claim 25 are repeated here by reference.

Regarding amended claim 25, Brooker does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined aerosol deposition in the lung. Brooker also does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting flow rate or tidal volume based on inhalation parameters. Brooker states that "[i]t will be remembered that the pulmonary dosing system of the present invention does not include a respirator or the like, and is intended for use with patients who can breathe normally." (col. 4, lines 31-35). The breathing pattern is Brooker is not adjustable in the device. The breathing pattern in Brooker is not controlled, since deposition is preferably measured during inhalation treatment by using the radioactive tracer Tc99m. Once the data using the tracer has been collected, a physician is required to train and guide the patient. The device is

not capable of being individually adjusted by adjusting a respiratory flow or a tidal volume of the inhalation device based on the inhalation parameters.

Servidio does not provide what Brooker lacks. More specifically, Servidio does not teach or suggest individually adjusting an inhalation device to a patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined aerosol deposition in the lung. Servidio also does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting flow rate or tidal volume based on the inhalation parameters. Instead, Servidio teaches a pressure support ventilatory assist device with pressure regulation. Servidio mentions tidal volume; however, the tidal volume is just an inputted or outputted value, and one of a number of parameters that are measured during use of the device.

The Applicant respectfully notes that, in the present office action, the Examiner "agrees with Bernhard Muellinger's declaration that Servidio does not teach or suggest individually adjusting an inhalation device to a patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters and that Servidio does not teach or suggest adjusting flow rate or tidal volume based on the inhalation parameters." (present office action dated March 20, 2009, page 12, lines 8-12).

Servidio relates to a completely different field from the present invention. Servidio teaches supplying pressurized air to a patient in the treatment of obstructive sleep apnea. The treatment of sleep apnea, i.e. the intermittent obstruction of the upper airway occurring during sleep, is in no way linked to the administering of a controlled inhalation of therapeutic aerosol for a patient during breathing maneuvers according to claim 25. Servidio does not teach or suggest any type of aerosol dosing.

Furthermore, there is no motivation to combine Brooker's dosing system with Servidio's sleep apnea breathing device, nor would the combination teach or suggest the present invention. Each of the references teaches very different devices that perform different functions. A person of ordinary skill in the art of inhalers would not combine elements from pulmonary dosing system art with elements of sleep apnea device art.

Brooker and Servidio, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Brooker in view of Servidio. Claim 48 (previously claim 23), being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations it contains. Reconsideration and withdrawal of the rejection are respectfully requested.

9. Claims 22, 29, 30, 35, 36, 37 and 45-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker in view of Willemot (5,560,353). Applicant respectfully disagrees with this rejection. The arguments regarding the anticipation and nonobviousness of claim 25, upon which claims 45, 50 (previously claim 22) and 51-54 (previously claims 29, 30, 35, and 36, respectively), depend, and the arguments regarding the anticipation of claims 43 and 44, upon which claims 46 and 47 depend, respectively, are repeated herein by reference.

Regarding amended claims 25, 43, and 44, Willemot does not provide what Brooker lacks. More specifically, Willemot does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters to obtain a predetermined aerosol deposition in the lung. Willemot also does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting flow rate or tidal volume based on the individual patient parameters or the aerosol parameters. Instead, Willemot teaches a system that supplies puffs of gas containing particles of an active product to a patient. This gas is only used to drive the aerosol generation system. The gas does not provide the whole inhalation flow rate or inhalation volume. Willemot teaches a metered dose inhaler. “Breath phases of the patient are sensed for initiating each of the puffs at the correct point in the breath cycle, and for counting the puffs. The sequence of puffs is programmably controlled and the puffs in a predetermined sequence according to a puff sequence program.” (Abstract). The system senses breath phases of a patient; it does not adjust them in any way. Therefore, Willemot does not adjust an inhalation device to a patient by adapting a dosage of at least one aerosol, nor does Willemot adjust flow rate or tidal volume based on individual patient parameters or aerosol parameters.

The Applicant respectfully notes that, in the present office action, the Examiner "agrees with Bernhard Muellinger's declaration that Willemot does not teach or suggest individually adjusting an inhalation device to a patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters and Willemot does not teach or suggest adjusting flow rate or tidal volume based on inhalation parameters." (present office action dated March 20, 2009, page 12, lines 17-21).

Brooker and Willemot, alone or in combination, do not teach or suggest all of the elements of claims 25, 43 and 44. Therefore, it is respectfully suggested that independent claims 25, 43 and 44 are not obvious over Brooker in view of Willemot. Claims 45-47, 50 (previously claim 22) and 51-54 (previously claims 29, 30, 35, and 36, respectively) should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

10. Claims 24, 25, 28, 38-40 and 42-44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989) in view of Brooker. Applicant respectfully disagrees with this rejection. The arguments regarding the anticipation and nonobviousness of claims 25, 43 and 44 over Brooker, are repeated herein by reference.

Regarding amended claims 25, 43, and 44, Brand does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters to obtain a predetermined aerosol deposition in the lung. Brand also does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting flow rate or tidal volume based on the individual patient parameters or the aerosol parameters.

In the present invention as claimed in claims 25, 43 and 44, each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed.

In Brand, flow rates and volumes can be selected by the user by entering values for inhalation volume and inhalation flow rate. However, this selection does not result in an optimal dose of at least one active ingredient of at least one aerosol being applied to a desired section of a

lung of a patient during a controlled inhalation. Brand does not teach or suggest a device that is individually adjusted by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters to obtain a predetermined aerosol deposition in the lung. In addition, Brand does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters or aerosol parameters.

While Brand teaches having the user select flow rates and volumes by entering values for inhalation volume and inhalation flow rate, even a trained physician or a trained nurse is not able to guide a patient so that the patient inhales with an optimum flow rate and volume. The Applicant has shown published clinical data from Köhler et al. that show that, even when patients are guided, they do not inhale with the optimum flow rate and inhalation volume, as shown in the published clinical data from Köhler et al (Journal of Aerosol Medicine, 2005, submitted in the IDS dated July 11, 2006). Köhler specifically states that "All the CF patients have been regularly trained for several years in manually triggered inhalation by a physiotherapist (i.e. to press the interrupter immediately prior to the start of inhalation and to release the interrupter immediately after the end). They were instructed to inhale deeply and slowly." (Köhler, page 388, column 1, third full paragraph). Despite these instructions, "it was found that inhalation with the electronically controlled inspiration flow by means of AKITA permitted a deposition that was 46% (range 3-162%) higher and more peripheral than the conventional mode…. The improvement noted for deposition was obviously attributable to the controlled breathing maneuver alone." (Köhler, page 391, first full paragraph).

The Applicant respectfully notes that, in the present office action, the Examiner "agrees with Bernhard Meullinger's declaration that Brand does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters and Brand does not teach or suggest adjusting flow rate or tidal volume based on inhalation parameters." (present office action dated March 20, 2009, page 11, lines 17-21).

As discussed above with respect to the rejection of claims 25, 43, and 44, Brooker does not provide what Brand lacks.

Brand and Brooker, alone or in combination, do not teach or suggest all of the elements of claims 25, 43 and 44. Therefore, it is respectfully suggested that independent claims 25, 43 and 44 are not obvious over Brand in view of Brooker. Claims 25, 28, 38, 42 and 49 (previously claim 24), being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Brand in view of Brooker and Servidio. Applicant respectfully disagrees. The arguments regarding the obviousness of claim 25, upon which claim 48 (previously claim 23) depends, over Brand in view of Brooker, is repeated herein by reference.

Regarding amended claim 25, Servidio does not provide what Brand and Brooker lack. More specifically, Servidio does not teach or suggest individually adjusting an inhalation device to a patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters to obtain a predetermined aerosol deposition in the lung. Servidio also does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting flow rate or tidal volume based on the inhalation parameters. Instead, Servidio teaches a pressure support ventilatory assist device with pressure regulation. Servidio mentions tidal volume; however, the tidal volume is just an inputted or outputted value, and one of a number of parameters that are measured during use of the device.

Brand, Brooker and Servidio, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Brand, Brooker in view of Servidio. Claim 48 (previously claim 23), being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations it contains. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 22, 29, 30, 35, 36, 37 and 45-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brand in view of Brooker and Willemot (5,560,353). Applicant respectfully disagrees with this rejection. The arguments regarding the anticipation and nonobviousness of claim 25, upon which claims 45, 50 (previously claim 22) and 51-54

(previously claims 29, 30, 35, and 36, respectively), depend, and the arguments regarding the anticipation of claims 43 and 44, upon which claims 46 and 47 depend, respectively, over Brand and Brooker are repeated herein by reference.

Regarding amended claims 25, 43, and 44 Willemot does not provide what Brand and Brooker lacks. More specifically, Willemot does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the individual patient parameters or the aerosol parameters to obtain a predetermined aerosol deposition in the lung. Willemot also does not teach or suggest adjusting a breathing maneuver of a patient according to capabilities of the patient by adjusting flow rate or tidal volume based on the individual patient parameters or the aerosol parameters. Instead, Willemot teaches a system that supplies puffs of gas containing particles of an active product to a patient. This gas is only used to drive the aerosol generation system. The gas does not provide the whole inhalation flow rate or inhalation volume. Willemot teaches a metered dose inhaler. "Breath phases of the patient are sensed for initiating each of the puffs at the correct point in the breath cycle, and for counting the puffs. The sequence of puffs is programmably controlled and the puffs in a predetermined sequence according to a puff sequence program." (Abstract). The system senses breath phases of a patient; it does not adjust them in any way. Therefore, Willemot does not adjust an inhalation device to a patient by adapting a dosage of at least one aerosol, nor does Willemot adjust flow rate or tidal volume based on individual patient parameters or aerosol parameters.

Brand, Brooker and Willemot, alone or in combination, do not teach or suggest all of the elements of claims 25, 43 and 44. Therefore, it is respectfully suggested that independent claims 25, 43 and 44 are not obvious over Brand in view of Brooker and Willemot. Claims 45-47, 50 (previously claim 22) and 51-54 (previously claims 29, 30, 35, and 36, respectively) should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully

requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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